THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CAREDX, INC., *et al*. Plaintiff, v. NATERA INC., Defendant,	C.A. No.: 1:19-cv-00567-CFC-CJB (CONSOLIDATED)
CAREDX, INC. v. EUROFINS VIRACOR, INC. Defendant, and THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY Nominal Defendant.	C.A. No. 1:19-cv-1804-CFC-CJB

EUROFINS VIRACOR INC. AND NATERA, INC.'S OPENING BRIEF IN SUPPORT OF THEIR JOINT MOTION FOR CERTIFICATION FOR INTERLOCUTORY APPEAL

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

Eurofins Viracor, Inc. ("Eurofins") and Natera, Inc. ("Natera") seek certification under 28 U.S.C. §1292(b) to address whether post-hoc assertions by a paid expert using third party publications can raise, alone, a ***genuine*** dispute over the issue of "conventionality" under 35 U.S.C. § 101 in the face of contrary admissions in the written description of a patent. In U.S. Patent Nos. 8,703,652 (the "'652 Patent"), 9,845,497 (the "'497 Patent"), and 10,329,607 (the "'607 Patent") (collectively the "CareDx Patents") at issue here,[1] the alleged inventors admitted that "the practice of the present inventions employs, unless otherwise indicated, ***conventional*** techniques." Although the quoted language included the caveat "unless otherwise indicated," there is no indication otherwise in the CareDx Patents. They are bereft of any explanation of how to carry out the claimed steps, instead relying on commercially available products and machines operated conventionally based on the general knowledge of one of skill in the art.

Absent approval of this issue for interlocutory appeal by this Court, Eurofins and Natera cannot test this threshold legal issue and be spared years of needless litigation. Prevailing on the Section 101 issue after discovery and trial would not

[1] The CareDx Patents share a common written description. All three CareDx Patents are asserted against Natera in Case No. 19-cv-567. Only the '652 Patent is asserted against Eurofins in Case No. 19-cv-1804.

permit Eurofins or Natera to have avoided those expenses when the intrinsic record here provides relief at the outset of the case. *See Bilski v. Kappos*, 561 U.S. 593, 601 (2010) (§ 101 eligibility a threshold test); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1360 (Fed. Cir. 2017) ("[W]e have repeatedly affirmed § 101 rejections . . . before claim construction or significant discovery has commenced."); *I/P Engine, Inc. v. AOL Inc.*, 576 Fed. App'x 982, 996 (Fed. Cir. 2014) (Mayer, J., concurring) ("From a practical perspective, there are clear advantages to addressing section 101's requirements at the outset of litigation . . . [it] can spare both litigants and courts years of needless litigation.").

Near the outset of this litigation, the Court allowed early summary judgment motions based on Section 101 after having expressed its own doubts about the CareDx Patents' validity—doubts that appeared from the face of the patents themselves. Ultimately, however, the Court denied summary judgment on the basis of a single material fact issue—whether the claims' recited techniques for performing multiplex or high throughput sequencing, and in the case of the '497 Patent, digital PCR, were routine and conventional. *See* Case No. 19-cv-1804, D.I. 76 at 1-2; Case No. 19-cv-567, D.I. 115 at 1-2.

Such ruling was based on fact issues that the Court found were raised by the patentee's expert and third party articles that only obliquely criticized the multiplex / high throughput sequencing and digital PCR technology as having certain

technical limitations. But much like the Ford Model T rendered the automobile a conventional mode of transportation by the 1920s, despite having maintenance, reliability, speed, and range shortcomings not found in cars of today, the commercial machines specified by the CareDx Patents are no less conventional even if they were still "significantly limited by [] cost, turnaround time[], and level of sensitivity imposed by background noise" or faced barriers due to "complexity of technical procedures, robustness, accuracy, and cost." Case No. 19-cv-567, D.I. 115 at 2-3; Case No. 19-cv-1804, D.I. 76 at 2-3. None of these shortcomings is claimed or even addressed in the CareDx Patents. The articles and commentary by CareDx's expert thus should have been incapable of creating a *genuine* issue as a matter of law in the face of the patent's admissions of conventionality and its reliance on the commercial availability of the multiplex or high throughput sequencing and digital PCR machines specified to carry out the steps of the claims.

No case law to date has directly addressed in the context of Section 101 whether third party publications or the post-hoc rationalizations of a patent holder's expert may create a genuine issue over the patent's claims and the inventors' admissions in the patent's written description. In an analogous context, however, courts consistently favor the intrinsic record, *i.e*. the claims and written description, over extrinsic evidence. *See Vitronics Corp. v. Conceptronic, Inc.*, 90

F.3d 1576, 1582 (Fed. Cir. 1996) ("[I]ntrinsic evidence is the most significant source of the legally operative meaning of disputed claim language.").

Eurofins and Natera thus submit that the order denying summary judgment "involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b). Accordingly, Eurofins and Natera respectfully seek the Court's certification under 28 U.S.C. § 1292(b).

II. NATURE AND STAGE OF THE PROCEEDINGS AND CONCISE STATEMENT OF FACTS

A. Procedural Background

On March 26, 2019, CareDx filed its complaint against Natera asserting infringement of the '658 and '794 Patents. Case No. 19-cv-567, D.I. 1. Natera moved to dismiss the complaint on May 16, 2019, in pertinent part on grounds that the asserted patent claims are invalid under 35 U.S.C. § 101. Case No. 19-cv-567, D.I. 9.

On September 26, 2019, CareDx filed its Complaint against Eurofins, asserting infringement of the '652 Patent only. Case No. 19-cv-1804, D.I. 1.

Eurofins filed a motion to dismiss on October 16, 2019, on grounds that the claims of the '652 Patent are invalid under 35 U.S.C. § 101. Case No. 19-cv-1804, D.I. 6.

On February 10, 2020, Magistrate Judge Burke made a report and recommendation (the "Report and Recommendation") recommending denial of both Natera's and Eurofins' motions based on his determination that the claims are not directed to a natural phenomenon. D.I. 30. Natera and Eurofins filed objections to the Report and Recommendation on February 24, 2020, and CareDx filed responses to those objections on March 3, 2020. Case No. 19-cv-567, D.I. 63, 68; Case No. 19-cv-1804, D.I. 37, 41.

On March 12, 2020, CareDx filed a First Amended Complaint against Natera, additionally asserting infringement of the '607 Patent. Case No. 19-cv-567, D.I. 74. On March 13, 2020, the Court vacated the Report and Recommendation in the Natera case and stated that "Natera is free to file a motion to dismiss the First Amended Complaint." Case No. 19-cv-567, D.I. 76. On April 4, 2020, Natera filed a motion to dismiss the First Amended Complaint on grounds that the asserted claims are invalid under 35 U.S.C. § 101. Case No. 19-cv-567, D.I. 86.

On April 21, 2020, in the Eurofins case, the Court issued an order adopting the result of Magistrate Judge Burke's Report and Recommendation, but not his reasoning. Case No. 19-cv-1804, D.I. 53. In agreeing that the case should not be

dismissed, the Court stated that "[a]lthough language in the written descriptions of the two[2] asserted patents suggests that the patented steps are neither new nor unconventional, see generally *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, LLC, 915 F.3d 743, 757 (Fed. Cir. 2019) (claims that "recite only a natural law together with conventional steps to detect that law, . . . are ineligible under § 101"), I agree with the Magistrate Judge that it would be premature to make at this time a definitive ruling on whether the claims recite patent eligible subject matter." Case No. 19-cv-1804, D.I. 53 at 2. The Court also stated that "the patents' specifications raise doubts about the patents' validity," and invited an early summary judgment motion. *Id.*

On April 30, 2020, the Court stayed the cases to allow Eurofins and Natera to file summary judgment motions for invalidity under 35 U.S.C. § 101, because as the Court recognized, "the patent itself raises concerns as to whether the patent survives 101." Ex. A (4/30/20 Hearing Tr.) at 7:3-4. Natera thereafter withdrew its pending motion to dismiss on Section 101 grounds. Case No. 19-cv-567, D.I. 97. Eurofins and Natera filed their motions for summary judgment on June 11, 2020. Case No. 19-cv-567, D.I. 100; Case No. 19-cv-1804, D.I. 61. The Court denied the motions on December 1, 2020, holding that there is a disputed fact as to

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[2] The Court referred to "two" patents because of coordination of the Eurofins and Natera briefing on Section 101 issues.

the nonconventionality of the claims' multiplex or high throughput sequencing elements, and with respect to the '497 patent (asserted only against Natera) also as to the digital PCR element.[3] Case No. 19-cv-567, D.I. 115 at 2-3; Case No. 19-cv-1804, D.I. 76 at 2-3.

B. The CareDx Patents

As the Court recognized, the written descriptions of the CareDx Patents contain the patentee's own admissions regarding the conventionality of the recited claim limitations. The written description states that:

> The **practice of the present invention** employs, unless otherwise indicated, **conventional techniques** of immunology, biochemistry, chemistry, molecular biology, microbiology, cell biology, genomics and recombinant DNA, **which are within the skill of the art**.

Case No. 19-cv-567, D.I. 102-2 at B0012 ('652 Patent) at 5:36-40; Case No. 19-cv-1804, D.I. 63-3 ('652 Patent) at 5:36-40 (emphasis added).

The patents do not go on to "otherwise indicate" anything nonconventional. To the contrary, the written description repeatedly makes clear that the claimed techniques can be performed using suitable techniques known in the prior art:

- "Genotyping of the transplant donor and/or the transplant recipient may be performed by **any suitable method known in the art**

[3] Only the claims of the '497 Patent recite a digital PCR element. The claims of the '652 and '607 Patents do not recite digital PCR.

including those described herein such as sequencing, nucleic acid array or PCR." *Id.* at B0019, 20:31-34.

- "The presence or absence of one or more nucleic acids from the transplant donor in the transplant recipient may be determined by **any suitable method known in the art** including those described herein such as sequencing, nucleic acid arrays or PCR." *Id.* at B0020, 21:5-9.

- "Detection, identification and/or quantitation of the donor-specific markers (e.g. polymorphic markers such as SNPs) can be performed using real-time PCR, chips (e.g., SNP chips), high-through-put shotgun sequencing of circulating nucleic acids (e.g. cell-free DNA), **as well as other methods known in the art** including the methods described herein." *Id.* at B0014, 9:8-14.

Finally, the written description describes commercially available equipment and kits to perform the claimed methods, citing to publications as early as nine years before the priority date of the CareDx Patents:

- "In some embodiments, high-throughput sequencing involves the use of technology available by Helicos BioSciences Corporation (Cambridge, Mass.) such as the Single Molecule Sequencing by Synthesis (SMSS) method." *Id.* at 15:22-25.

- "In some embodiments, high-throughput sequencing involves the use of technology available by 454 Lifesciences, Inc. (Branford, Conn.) such as the Pico Titer Plate device." *Id.* at 15:38-40.

- "In some embodiments, high-throughput sequencing is performed using Clonal Single Molecule Array (Solexa, Inc.) or sequencing-by-synthesis (SBS) utilizing reversible terminator chemistry. These technologies are described in part in U.S. Pat. Nos. 6,969,488; 6,897,023; 6,833,246; 6,787,308; and US Publication Application Nos. 200401061 30: 20030064398; 20030022207; and Constans, A, The Scientist 2003, 17(13): 36." *Id.* at 15:53-60.

- "Other high-throughput sequencing systems include those disclosed in Venter, J., et al. Science 16 Feb. 2001; Adams, M. et al., Science 24 Mar. 2000; and M. J. Levene, et al. Science 299:682-686, January 2003; as well as US Publication Application No. 20030044781 and 2006/0078937." *Id.* at 16:9-13.

C. CareDx's Opposition

In denying Eurofins' and Natera's motions for summary judgment, this Court found a genuine dispute of material fact as to whether the written description and claims disclose nonconventional techniques for high throughput / multiplex sequencing and, in the case of the '497 patent, also as to digital PCR. Case No. 19-cv-567, D.I. 115; Case No. 19-cv-1804, D.I. 76. The Court stated that CareDx denied this factual assertion based on, "among other things, six scientific articles that discuss the limitations and nascent nature of some of the specifically disclosed techniques as well as the declaration of its expert, Dr. Brian Van Ness." *Id*. at 2.

Eurofins and Natera respectfully submit that, as a matter of law, the articles and expert testimony relied on by CareDx should have been incapable of raising a genuine issue of material fact in the face of the patents' admissions in their claims and written description. At most, the articles and testimony discuss technical shortcomings of aspects of the multiplex or high throughput sequencing and digital PCR technology that the patents do not discuss or claim. *See* D.I. 67 at 13-18. As the Federal Circuit has repeatedly made clear, however, if "the evidence that aspects of the invention [were] not well-understood, routine, and conventional does

not pertain to the invention ***as claimed***, it will not create a factual dispute as to these claims." *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 890 F.3d 1354, 1357 (Fed. Cir. 2018) (emphasis added).

For example, CareDx cited a 2020[4] scientific article stating that "standard targeted [multiplex or high-throughput sequencing] is significantly limited by its cost, turnaround time[], and level of sensitivity imposed by background noise." Case No. 19-cv-567, D.I. 104-1 at C0524; Case No. 19-cv-1804, D.I. 65-1 at C0524. But nothing in the claims addresses these alleged limitations.

Similarly, CareDx cited a 2008 article stating that "[a]s digital PCR relies on statistical analysis and a series of algorithms indicating probability that a fetus is normal or affected, the question arises whether this method will be relegated for use as a screening tool or whether it will indeed pass the necessary scientific and regulatory hurdles permitting it to be used diagnostically." Case No. 19-cv-567, D.I. 104-1 at C0601; Case No. 19-cv-1804, D.I. 65-1 at C0601. But the claims of the CareDx Patents are not directed to overcoming scientific and regulatory hurdles for the use of digital PCR.

[4] Eurofins respectfully submits that an article from 2020, 11 years after the relevant time period, has no bearing at all on whether the recited claim techniques were conventional at the time of patent application in 2009.

And another article from 2009 on which CareDx relied states that next-generation sequencing platforms encountered several issues, "including biases in sample library generation, difficulties mapping short reads, variation in sequence coverage depth of unique and repetitive elements, difficulties detecting indels with short reads, the systematic errors of the NGS technologies and the impact of all these features on variant calling accuracy." Case No. 19-cv-567, D.I. 104-1 at C0610; Case No. 19-cv-1804, D.I. 65-1 at C0610. But the claims do not address any of these purported issues. Indeed, the patent relies on the conventionality of the techniques, implemented by commercially available multiplex or high throughput sequencing machines, to support the claims.

To this day, scientists continue to refine high throughput, multiplex sequencing and digital PCR to make them more efficient and accurate. If the statements relied upon by the Court render the ***techniques as claimed*** non-conventional, then the techniques would not be conventional even today (or perhaps ever), despite their routine use over the last 20 years, simply because scientists are continually improving them.

Eurofins and Natera respectfully request certification for interlocutory appeal of the Court's summary judgment order, because there is substantial difference in opinion in the case law as to whether, as a matter of law, a patentee

can survive summary judgment in view of the patent's admissions in the claims and written description.

III. ARGUMENT

Under 28 U.S.C. § 1292(b), the criteria for certification of an interlocutory appeal are: (1) the order involves a controlling question of law, as to which (2) there is substantial ground for difference of opinion, and (3) an immediate appeal will materially advance the ultimate termination of the litigation. 28 U.S.C. § 1292(b); *see also Voda v. Cordis Corp.*, 476 F.3d 887, 890 (Fed. Cir. 2007). As further explained below, Eurofins and Natera respectfully assert that the order and issue here meet each of these criteria, and that absent interlocutory appeal, Eurofins and Natera (and the Court) cannot be spared the "years of needless litigation" that early § 101 motions seek to avoid. *I/P Engine*, 576 Fed. App'x at 996.

A. The Court's Order Concerns a Controlling Question of Law

In order for a court to certify its order for interlocutory appeal under 28 U.S.C. § 1292(b), it must concern a controlling question of law. *Voda*, 476 F.3d at 890. "In general, a question of law is 'controlling' within the meaning of Section 1292(b) only if [the] resolution of that issue could have an immediate impact on the course of the litigation." *Fujitsu Ltd. v. Tellabs, Inc.*, 539 Fed. App'x 1005, 1007 (Fed. Cir. 2013). A question is "controlling" for purposes of

Section 1292(b) "if interlocutory reversal might save time for the district court, and time and expense for the litigants." C. Wright, A. Miller, & E. Cooper, 16 FEDERAL PRAC. & PROC. § 3930, at 499 (2012).

There can be little doubt that the subject order involves a controlling question of law. Should the Federal Circuit determine that the asserted CareDx patent claims are invalid under Section 101, the cases against Eurofins and Natera would be dismissed. Answering this question at this juncture will ensure that neither this Court nor the parties unnecessarily spend substantial time and resources on litigation when the Section 101 issue may be determined as a matter of law if the appeals court finds that the admissions of the patents cannot be overcome by third party articles and after-the-fact expert testimony. Even if the Federal Circuit were to affirm the finding of a material fact issue, such would provide valuable guidance for further proceedings in the district court. Accordingly, Natera and Eurofins respectfully assert that the first prong of certification under Section 1292(b) is satisfied here.

B. There is Substantial Ground For Difference of Opinion

The second requirement for certification is that the question at issue be one "as to which there is substantial ground for difference of opinion." 28 U.S.C. § 1292(b). The Federal Circuit has held that there is a substantial ground for difference of opinion where there may be two different, but plausible,

interpretations of a line of cases. *See Vereda, LTDA v. U.S.*, 271 F.3d 1367, 1374 (Fed. Cir. 2001) (agreeing with the trial court that a '"substantial ground for difference of opinion"' was present regarding interaction between two Federal Circuit cases) (citation omitted).

Under *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217-18 (2014) (citing *Mayo Collab. Srvcs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 77-81 (2012)), Section 101 is analyzed by looking at whether the claims at issue are directed to a patent ineligible concept, and then whether the claims provide "an 'inventive concept'—*i.e.*, an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'" *Id.* (quoting *Mayo*, 566 U.S. at 72-73). With respect to step two, the Supreme Court has held that a method reciting a law of nature is not patentable where the steps "involve well-understood, routine, conventional activity previously engaged in by researchers in the field." *Mayo*, 566 U.S. at 73.

Relevant here is the question of whether there can be a genuine dispute of fact in view of the admissions in the patents regarding the conventionality of the recited claim limitations. There is substantial ground for difference of opinion in the case law on this issue. On one hand, the Supreme Court has affirmed summary judgment in view of inventors' statements in a patent specification, much like the

admissions in the ’652 patent. In *Mayo*, the Supreme Court relied upon statements in the patent specification itself to conclude that the claims were invalid:

> [T]he “determining” step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use. **As the patents state, methods for determining metabolite levels were well known in the art. ’623 patent, col.9, ll.12–65, 2 App. 11.** Indeed, **scientists routinely measured metabolites** as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of thiopurine compounds. **’623 patent, col.8, ll.37–40, *id*., at 10**. Thus, this step tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field.

Mayo, 566 U.S. 66 at 79 (emphasis added).[5] Likewise, the Federal Circuit has affirmed summary judgment under Section 101 where the patent’s written description in the specification identifies a technology as well-known or performed using commercially available tools or kits. *See e.g.*, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377 (Fed. Cir. 2015) (“The specification of the ’540 patent confirms that the preparation and amplification of DNA sequences in

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[5] The admissions relied upon by the Supreme Court in *Mayo* for the patent at issue in that case, U.S. Patent No. 6,555,623, are strikingly similar to the admissions in the ’652 patent. *Compare* ’623 patent at 9:13-15 (“The level of a 6-MP metabolite can be determined by methods well known in the art.”) *with* ’652 patent at 20:31-34 (“Genotyping of the transplant donor and/or the transplant recipient may be performed by any suitable method known in the art including those described herein such as sequencing, nucleic acid array or PCR.”) *and* 21:5-9 (“The presence or absence of one or more nucleic acids from the transplant donor in the transplant recipient may be determined by any suitable method known in the art including those described herein such as sequencing, nucleic acid arrays or PCR.”).

plasma or serum were well-understood, routine, conventional activities performed by doctors in 1997."); *Cleveland Clinic Found. v. True Health Diagnostics, LLC*, 859 F.3d 1352, 1360-63 (Fed. Cir. 2017) ("The specifications of the testing patents confirm that known testing methods could be used to detect MPO, and that there were commercially available testing kits for MPO detection," and "the claims here instruct that MPO levels be detected or determined using any of these known techniques.").

The Federal Circuit has furthermore recognized that "it is also possible, as numerous cases have recognized, that a § 101 analysis may sometimes be undertaken without resolving fact issues," and that "the mere existence in the record of dueling expert testimony does not necessarily raise a genuine issue of material fact." *Mortgage Grader Inc. v. First Choice Loan Services Inc., NYLX, Inc.*, 811 F.3d 1314, 1325 (Fed. Cir. 2016).

On the other hand, the Federal Circuit has also held that "[t]he question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact." *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018). Under *Berkheimer*, a patent holder can presumably defeat summary judgment by providing evidence sufficient to show that the claim elements are not conventional. But *Berkheimer* did not involve or make clear whether that would be allowed when the inventors

made contrary admissions in the written description, nor did *Berkheimer* set out any standards or detail the type of evidence that might be sufficient to overcome a patent's intrinsic admissions. Nonetheless, CareDx cited *Berkheimer* in arguing that "there is overwhelming evidence that the concepts Defendants identify were not routine and conventional in the 2009 time frame in the context of cell-free DNA." Case No. 19-cv-567, D.I. 103 at 28-29; Case No. 19-cv-1804, D.I. 64 at 28-29.

CareDx's application of *Berkheimer* appears to contradict the Supreme Court's description of Section 101 as a "threshold test," as well as the Supreme Court's and Federal Circuit's prior rulings in *Mayo* and *Cleveland Clinic* (and others) finding claims invalid based on a patentee's admissions in the specification.[6] At the very least, the divergence in the case law shows that there is a "substantial ground for difference of opinion" that merits interlocutory review.

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[6] The Federal Circuit is itself internally divided on this issue. As Judge Reyna explained, prior to *Berkheimer*, "there is no precedent that the § 101 inquiry is a question of fact." *Aatrix*, 890 F.3d at 1362 (dissenting opinion). According to Judge Reyna, *Berkheimer* "alter[ed] the § 101 analysis in a significant and fundamental manner by presenting patent eligibility under § 101 as predominately a question of fact" and "reduc[ed] the entire step two inquiry into what is routine and conventional, rather than determining if an inventive concept expressed in the claims transforms the nature of the claims into a patent-eligible application," thereby "divorc[ing]" step two "from the claims." *Id.* Judge Reyna ultimately concluded that *Berkheimer* is "counter to guidance from the Supreme Court and our own precedent." *Id.* at 1365.

See Pioneer Hi-Bred Int'l, Inc. v. J.E.M. Ag Supply, Inc., 200 F.3d 1374, 1375-76 (Fed. Cir. 2000) (granting interlocutory review to clarify the legal standard under Section 101 as applied to seeds and seed-grown plants). Here, Federal Circuit review of this Court's summary judgment decision would clarify the legal standard for determining whether a genuine fact dispute may be presented when the written description admits that the claimed limitations are conventional.

C. Certification Will Materially Advance the Ultimate Termination of the Litigation

The final requirement for certification is that "an immediate appeal from the order may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b). The Federal Circuit has emphasized "that the purpose of interlocutory appeals was to create a vehicle to avoid unnecessary expenditures of party and court resources." *Fujitsu*, 539 Fed. App'x at 1008 (citing S. Rep. No. 2434, Report of the Committee on Appeals from Interlocutory Orders of the District Courts, Sept. 23, 1953, *reprinted in* 1958 U.S.C.C.A.N. 5255, 5260-61); *see also Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 144 Fed. App'x 106, 107 (Fed. Cir. 2005) (permitting an interlocutory appeal where such appeal would "conserve judicial resources).

Plainly, resolution here of the Section 101 issue will materially advance termination of this litigation. If Section 101 is decided in Eurofins' and Natera's favor, the cases against them would be dismissed, conserving this Court's and the

parties' resources. Even if the Federal Circuit decided against Eurofins and Natera, it could provide much needed guidance on what is required to show that claims are directed to "routine and conventional" methods—which would materially advance this litigation by providing a standard before the parties complete discovery. Thus, the third prong for certification under Section 1292(b) is satisfied here as well.

IV. CONCLUSION

For the foregoing reasons, Eurofins and Natera respectfully request that the Court certify its December 1, 2020 Order for interlocutory appeal to the Federal Circuit.

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CERTIFICATE OF COMPLIANCE

Pursuant to the Court's November 6, 2019 Standing Order, I hereby confirm that this brief complies with the type and number limitations set forth in the Standing Order. I certify that this document contains 4,419 words, which were counted using the word count feature in Microsoft Word, in 14-point Times New Roman font. The word count does not include the cover page, table of contents and authorities, or the counsel blocks.

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